

Corporation obtaining approval, the name of its representative, and the address of its main office

Name: The Chemo-Sero-Therapeutic Research Institute

Applicant: Akinobu Funatsu, Director General

Address: 1-6-1 Okubo, Kumamoto-shi, Kumamoto 860-8568, Japan

Approved Type 1 Use Regulation

Name of the Type of Living Modified Organism	Marek's disease virus serotype 1 strain 207 with transferring of the F protein gene originating from the Newcastle disease virus [NDV-F, Herpesviridae Alphaherpesvirinae Mardivirus Gallid herpesvirus 2 (Marek's disease virus serotype 1)] (Cellmune N)
Contents of the Type 1 Use of Living Modified Organism	(1) Transportation and storage (including transportation and storage of inoculated animals with the viable, modified live vaccine) (2) In the case of a study to collect data on clinical research, which must be submitted as specified by Article 14 Paragraph 3 of the Pharmaceutical Affairs Law (Law No. 145 of 1955) (hereinafter referred to as "clinical trial"), use of Living Modified Organism in accordance with the notification of the clinical trial plan submitted according to Article 80-2 Paragraph 2 of the said Law and the protocol prepared according to Article 7 of the Ordinance for good clinical practice of new animal drugs (Ordinance of the Ministry of Agriculture, Forestry and Fisheries No. 75 of 1997) (3) Use in accordance with the application for approval as specified by Article 14 Paragraph 1 of the Pharmaceutical Affairs Law [except operations relevant to (4)] (4) Vaccination (to layer and broiler chickens) (5) Disposal of devices and residues after inoculation in accordance with the standard for disposal of infectious industrial waste provided in Article 12-2 of the Waste Disposal and Public Cleansing Law (Law No.137 of 1970) (6) Disposal excluding those in (5) (including cases that accompany the disposal of inoculated animals carrying the viable modified live vaccine) (7) Acts incidental to (1) to (6)
Method of the Type 1 Use of Living Modified Organism	-